

- III. Claims 23, 27, 31, and 35, relating to B1, B1'-Sub-[Glu^{B26}]-des-(B27-B30)-insulin-B26 amide insulin dimer, a pharmaceutical preparation comprising the dimer, a method of treating diabetes comprising administering the pharmaceutical preparation, and a diagnostic kit.

The Examiner also required restriction among the following Subspecies of claim 16:

- I. Claim 17, relating to an insulin analogue characterized by formula I and in which X is an amino acid with an amidated carboxylic acid group.
- II. Claim 18, relating to an insulin analogue characterized by formula I and in which X is the amino acid sarcosine.
- III. Claim 19, relating to an insulin analogue characterized by formula I where the X residues of the two beta chains are different.
- IV. Claim 20, relating to an insulin analogue characterized by formula I where X is an amino group.

REMARKS

Applicants elect the invention of Species I and Sub-species I, with traverse. This election covers claims 15-17, 21, 24, 25, 28, 29, 32, 33, and 36. Applicants note that the Examiner has incorrectly described claim 28 as a process for producing a pharmaceutical to treat diabetes. Claim 28 relates to a method for treating diabetes comprising administering a pharmaceutical composition comprised of the insulin analogue. Applicants' reasons for traversal of this restriction are as follows.

First, as provided in the M.P.E.P. at § 803, two elements must be satisfied to impose a claim restriction properly: 1.) that the claimed inventions be independent or distinct; *and* 2.) that there must be a “serious burden” on the Examiner to perform a search on each of the claimed inventions. In addition, the M.P.E.P also states that “[e]xaminers must provide reasons and/or examples to support conclusions [as to why each of the above elements is satisfied].” *Id.* Applicants respectfully contend that the Examiner has not provided any explanation as to why the above claim species and subspecies represent distinct inventions or why searching these inventions would create a serious burden. At page 4 of the restriction requirement, the Examiner’s alleged “reasons” are simply a recitation of the statutory requirements for prosecuting only one invention per application and for responding fully to the restriction requirement. Otherwise, the Examiner has not presented any substantive grounds, pertaining to the specific subject matter of the pending claims, as to why the above two elements are met.

Second, there is no serious burden on the Examiner to examine all of the pending claims as one invention. Specifically, as indicated by the Examiner, all of the pending claims fall into the same three classes (514, 530, and 435). In addition, the subclasses listed for claims 15, 16, 24, 28, 32, and 36 cover all of the subclasses listed for the other Species and Subspecies of claims. Thus, the Examiner will have already searched the classes and subclasses required to examine Species II and III and Subspecies II-IV by searching the elected claims. As set forth in M.P.E.P. § 808.02, “[w]here, however, the classification is the same and the field of search is the same and there is no clear indication of separate future classification and field of search, no

reasons exist for dividing among related inventions.” Again, the Examiner has not provided any reasons as to why the field of search would be different for each species and subspecies of claims.

Finally, regarding claims 17-20 (Subspecies I-IV), *arguendo*, even if the Examiner’s description of these claims as subspecies is correct, Applicants note that the Federal Rules allow prosecution of more than one subspecies in a single patent application. Specifically, “more than one species of an invention, not to exceed a reasonable number, may be specifically claimed in different claims in one national application, provided the application also includes an allowable claim generic to all the claimed species and all the claims to species in excess of one are written in dependent form.” 37 C.F.R. § 1.141. Claim 16 is a generic claim, as the Examiner has indicated at page 4, line 4 of the restriction requirement. Four subspecies of that generic claim is not an unreasonable number to examine and, as required by the rule, claims 17-20 are written in dependent form.

Conclusion

For the foregoing reasons, Applicants respectfully request that pending claims 15-36 be examined together. And, at the very least, claims 18-20 should be remerged with the elected claims.

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Respectfully submitted,

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